

**Evidence and explanation of record do not provide a motivation to combine references.**

The PTO alleges "The two references can be combined to form the instant invention." See Office Action , page 3. Yet, in order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine reference teachings. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01 (emphasis in original). A motivation to combine teachings of various references cannot be established by merely implying one of ordinary skill in the art is capable of creating the claimed invention from bits and pieces of the documents of record. MPEP § 2143.01. Nor can the motivation be established by discussing how the teachings of the references may allegedly be combined. MPEP § 2143.01. Identifying ingredients and forms within the teachings of references cannot be equated with a motivation to combine those teachings. As the evidence and explanation of record fail to provide any basis for the desirability of combining the cited references, the rejection is improper and should be withdrawn.

To prevent the use of hindsight based on the invention to defeat patentability of an invention, the Federal Circuit requires the PTO to show a motivation to combine the references that create the case of obviousness. In other words, the PTO must show reasons that the skilled artisan, confronted with the same problems as the inventor and lacking knowledge of the claimed invention, would choose the elements from the cited references for combination in the manner claimed. *In re Rouffet*, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998). Importantly, with respect to this motivation, the Federal Circuit placed the burden on the PTO to present "clear and particular" evidence showing motivation to combine. *In re Dembiczaik*, 50 USPQ.2d 1614 (Fed. Cir. 1999).

In this case, even if Katz were "to teach a transdermal device to deliver drugs, i.e. cardioactive, antivirals, etc.,," that fact would not be a clear and particular reason to select the angiotensin II antagonists of SmithKline Beecham for use in the device of Katz. Thus, the rejection is improper and should be withdrawn.

Since the PTO has not established a motivation or desirability for combining the

references, the PTO has merely used Applicants' specification as a hindsight road map to recreate the claimed invention. To prevent the use of hindsight, “[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.” *See MPEP § 2142.* That has not been done in this case. As a *prima facie* case of obviousness has not been established for claims 1-6, 8, and 10-39, the rejection is improper and should be withdrawn.

**Disclosure of a genus does not render each species within that genus *prima facie* obvious.**

The PTO admits that SmithKline Beecham is deficient. This deficiency, according to the PTO, is remedied by combining SmithKline Beecham's teachings with those of Katz. According to the PTO, Katz discloses “a transdermal device to deliver drugs, i.e. cardioactive, antivirals, etc.” See Office Action, page 3. Moreover, the PTO states that “they are broad,” and therefore “they encompass all the drugs that fall into that class of drug.” Office Action, page 3.

Yet the disclosure of a genus does not render each species within that genus *prima facie* obvious. *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992). For example, the genus of cardioactive drugs is too large to inherently describe every member within it. Cf. MPEP § 2144.08 II. A 4 a. “Some motivation to select the claimed species or subgenus must be taught by the prior art.” *Id.* Yet Katz fails to identify any cardioactive or antiviral drug, let alone a drug having angiotensin II antagonistic activity. The silence of Katz cannot provide a motivation to select any particular species, particularly a drug having angiotensin II antagonistic activity. Thus, the rejection is improper and should be withdrawn.

**CONCLUSION**

As the remarks of record address and avoids each rejection, withdrawal of each rejection and allowance of each claim is respectfully requested. No new matter has been added.

If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned counsel or Sean A. Passino (45,943) at 202-295-4166.

Respectfully submitted,

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